UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,996	02/18/2005	Hiroyuki Asada	05105/HG	3212

1933 7590 06/03/2008

FRISHAUF, HOLTZ, GOODMAN & CHICK, PC
220 Fifth Avenue
16TH Floor
NEW YORK, NY 10001-7708

EXAMINER	
WEBB, WALTER E	
ART UNIT	**PAPER NUMBER**
1612	

MAIL DATE	DELIVERY MODE
06/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,996	ASADA ET AL.	
	Examiner	Art Unit	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-17* is/are rejected.

7)☒ Claim(s) *13, 15, and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant argues that it is not necessary to amend claims to recite the time period for the stability and possibly also the degree of stability. Applicant cites In re Estes, (CCPA 1970) 164 USPQ 519 and In re Merchant, (CCPA 1978), 197 USPQ 785, 788 for support. Applicant also shows data showing improvement in storage when ε-aminocaproic acid is added. Applicants have attached and cited "Stability of Drugs and Dosage Forms" page 142 for support. The Examiner acknowledges applicant's submission of data, and cited case law. However, applicant's claims are not commensurate in scope with their showing. The claim language is silent in regard to stability. Conversely, the prior art has shown that ε-aminocaproic acid at 0.01-2.0% w/v% provides stability in regard to ophthalmic suspensions. See discussion of Kimura et al. below. In fact, Kimura et al. shows that the castor oils of Schneider and ε-aminocaproic provide the same type of stability. Therefore, person having ordinary skill in the art would expect ε-aminocaproic to also stabilize the ophthalmic suspension of Schneider. Furthermore, a showing of unexpected results is irrelevent in regard to the anticipated claims. (See rejection of claims 1 and 5 below as being anticipated by Schneider et al.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Schneider et al. (US 6,011,062). This rejection also applies to newly added claim 5.

Schneider et al. teach an ophthalmic solution comprising a prostaglandin at 0.001 to 0.005% at pH 6 +/- 0.2. (See col. 9, Example 2 (table).) Schneider teaches that latanoprost can be used in that invention in column 5, line 57. Schneider also teaches stabilizing the ophthalmic suspension with polyethoxylated caster oils. (See abstract, and col. 2, lines 16-35.)

Claims 1 and 5 of applicant's invention are anticipated by the reference insofar as it teaches an ophthalmic solution comprising latanoprost at 0.001% (w/v) and 0.005% (w/v), where the pH falls between 5 and 6.25.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al. (*supra*) as applied to claims 1 and 5 above, and further in view of Kimura et al., (US 5,556,848).

Schneider et al., taught above, differs from the instant claims insofar as it does not teach adding ε-aminocaproic acid to its ophthalmic suspension.

Kimura et al. teach an ophthalmic suspension containing ε-aminocaproic acid since it suppresses formation of agglomerates, prevents lowering of pH, and provides a suspension superior in redispersabiltiy and stability, where the ε-aminocaproic acid would be 0.01-2.0 w/v% relative to the entire suspension. (See col. 3 lines 26-33.) They also teach adding polyoxyethylene castor oils for the same purpose (See col. 3, lines 50-54.) Thus Kimura teaches using ε-aminocaproic acid and castor oils in the same ophthalmic solution for the same purpose. Kimura does not teach the use of latanoprost.

Because Schneider recognized the stability problems of latanoprost and addressed this problem by combining the compound with similar castor oils of Kimura et al., it would have been obvious to a person having ordinary skill in the art at the time of applicants invention to further add ε-aminocaproic acid at 0.01-2.0% w/v% to the composition of Schneider, motivated by the teaching of Kimura that ε-aminocaproic acid would serve the same purpose as the castor oils.

Moreover, "[i]t would be prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven 206 USPQ 1069, 1073. Thus, adding ε-aminocaproic acid with the castor oils of Schneider constitutes prima facie subject matter, since they both would function to stabilize the ophthalmic suspension.

Furthermore, the adjustment of the ε-aminocaproic acid to 1% or 0.1-2%, which falls within the range taught by Kimura is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, this type of modification is no more than an effort to optimize results.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612